

In the Claims:

Please amend claims 1, 3, 9, 15, 33, 35, 61, and 72 as indicated below.

After the amendments are made, the claims read as follows. This listing of claims will replace all prior versions, and listings, of claims in the application.

1. (Currently amended) A urethral suppository for insertion into a female urethra, said suppository comprising:

a. a non-meltable base member not for insertion into said urethra, said base member having a surface;

b. a non-meltable reinforcement having a length, said length having a first end and a second end, said first end attached to said base member and projecting from said base member; and

c. a meltable portion formed around said length of said reinforcement, said meltable portion having a diameter which tapers from said reinforcement second end to said reinforcement first end such that the taper occupies substantially the extent of the meltable portion from the second end of the reinforcement to the first end of the reinforcement, said meltable portion for insertion into said urethra, said non-meltable base member being immobile with respect to the meltable portion;

said base member having a width in one direction perpendicular to the reinforcement, which width is greater than the maximum width of the meltable portion in a direction perpendicular to the reinforcement.

2. (Original) The urethral suppository of claim 1 wherein said base member is shaped for handling by a user of said suppository.

3. (Currently amended) A urethral suppository for insertion into a female urethra, said suppository comprising:

- a. a non-meltable base member not for insertion into said urethra, said base member having a surface;
- b. a non-meltable reinforcement having a length, said length having a first end and a second end, said first end attached to said base member and projecting from said base member; and
- c. a meltable portion formed around at least a portion of said length of said reinforcement, said meltable portion having a diameter which tapers from said reinforcement second end toward said reinforcement first end such that the taper occupies substantially the extent of the meltable portion from the second end of the reinforcement to the first end of the reinforcement, said meltable portion for insertion into said urethra, said non-meltable base member being immobile with respect to the meltable portion and being wider than the meltable portion, wherein said base member is an ellipsoid having a major axis substantially perpendicular to the longitudinal axis of the reinforcement.

4. (Original) The urethral suppository of claim 3, wherein said ellipsoid is curved to promote maximal penetration of the meltable portion in the urethra.

5. (Original) The urethral suppository of claim 1 wherein the base member is grooved to facilitate handling by a user.

6. (Original) The urethral suppository of claim 1 wherein the surface of said base member is roughened to reduce slippage of suppository during insertion.

7. (Cancelled)

8. (Original) The urethral suppository of claim 1 wherein said base member is formed from one or more materials selected from the group consisting of synthetic polymer, urethane, cellulose, glass, metal, rubber, and cloth.

9. (Currently amended) A urethral suppository for insertion into a female urethra, said suppository comprising:

a. a non-meltable base member not for insertion into said urethra, said base member having a surface;

b. a non-meltable reinforcement having a length, said length having a first end and a second end, said first end attached to said base member and projecting from said base member; and

c. a meltable portion formed around at least a portion of said length of said reinforcement, said meltable portion having a diameter which tapers from said reinforcement second end toward said reinforcement first end, such that the taper occupies substantially the extent of the meltable portion from the second end of the reinforcement to the first end of the reinforcement, said meltable portion for insertion into said urethra, wherein said reinforcement first end is embedded within said base member, said non-meltable base member being immobile with respect to the meltable portion and being wider than the meltable portion.

10. (Original) The urethral suppository of claim 1 wherein said reinforcement projects substantially perpendicular from said base member.

11. (Previously presented) The urethral suppository of claim 1 wherein said reinforcement comprises a shape selected from the group consisting of ratchet, helix, cone and solid rod.

12. (Original) The urethral suppository of claim 11 wherein said shape is comprised of a lattice or mesh.

13. (Previously presented) The urethral suppository of claim 1 wherein said reinforcement is formed from one or more materials selected from the group consisting of urethane, cellulose, glass, metal, rubber, and cloth.

14. (Previously presented) The urethral suppository of claim 1 wherein upon insertion of the suppository into the urethra, the second end of said reinforcement is contained entirely within the meltable portion.

15. (Currently amended) ~~[[The]]~~ A urethral suppository of claim 1 for insertion into a female urethra, said suppository comprising:

a. a non-meltable base member not for insertion into said urethra, said base member having a surface;

b. a non-meltable reinforcement having a length, said length having a first end and a second end, said first end attached to said base member and projecting from said base member; and

c. a meltable portion formed around at least a portion of said length of said reinforcement, said meltable portion having a diameter which tapers from said reinforcement second end toward said reinforcement first end, said meltable portion for insertion into said urethra, wherein said base member is an ellipsoid having a major axis substantially perpendicular to the longitudinal axis of the reinforcement, wherein the second end of said reinforcement extends outside the meltable portion.

16. (Previously presented) The urethral suppository of claim 1 wherein the length of said reinforcement is in the range of about 40.0mm to about 80.0mm.

17. (Previously presented) The urethral suppository of claim 16 wherein said reinforcement has a diameter in the range of about 0.5mm to about 2.0mm.

18. (Original) The urethral suppository of claim 1 wherein said reinforcement comprises one or more restraints formed along the portion of the length of the reinforcement on which the meltable portion is formed.

19. (Original) The urethral suppository of claim 18 wherein said one or more restraints are selected from one or more of the group consisting of protrusions, intrusions, and combinations thereof.

20. (Original) The urethral suppository of claim 19 wherein said protrusions have shapes selected from the group of shapes consisting of spheres, hemispheres, triangles, rectangles, plates, rods, and combinations thereof.

21. (Original) The urethral suppository of claim 19 wherein said intrusions have shapes selected from the group of shapes consisting of spheres, triangles, rectangles, plates, rods, and combinations thereof.

22. (Original) The urethral suppository of claim 1 wherein said meltable portion comprises one or more materials selected from the group consisting of theobroma oil and modified theobroma oil products, glycerinated gelatin, hydrogenated vegetable oils, cellulose, poly (vinyl alcohol), poly (vinylpyrrolidone), polyacrylamide, poly (ethylene glycol), poly (phospho urethanes), polyoxyl stearate and ethylenoxide polymers.

23. (Original) The urethral suppository of claim 1 wherein said meltable portion comprises one or more therapeutic agents selected from one or more of the group of agents consisting of antibiotics, antimicrobials, antifungals, analgesics, anesthetics, steroidal anti-inflammatories, non-steroidal anti-inflammatories, mucous production inhibitors, hormones, and antispasmodics.

24. (Original) The urethral suppository of claim 1 wherein the diameter of the meltable portion formed around the second end is in the range of about 5 to about 12 millimeters.

25. (Original) The urethral suppository of claim 1 wherein the diameter of the meltable portion formed around the first end is in the range of about 4 to about 10 millimeters.

26. (Original) The urethral suppository of claim 1 wherein grooves are formed in said meltable portion.

27. (Original) The urethral suppository of claim 26 wherein said grooves are parallel to a longitudinal axis of the meltable portion.

28. (Original) The urethral suppository of claim 26 wherein said grooves are helical.

29. (Original) The urethral suppository of claim 26 wherein said grooves form a passage for liquid melted from said meltable portion.

30. (Previously presented) The urethral suppository of claim 1 wherein said meltable portion has a length greater than about 4.5cm.

31. (Original) The urethral suppository of claim 1 wherein the length of said meltable portion is from about 2.5 cm to about 5.0 centimeters.

32. (Original) The urethral suppository of claim 1 wherein said meltable portion melts within about 2 minutes to about 60 minutes.

33. (Currently amended) A urethral suppository for insertion into a female urethra, said suppository comprising:

a. a non-meltable base member not for insertion into said urethra, said base member having a surface;

b. a non-meltable reinforcement having a length, a first end attached to the base and a second end distal from the base, said reinforcement projecting from the base and comprising a urethral segment extending from said first end and a bladder segment extending from said urethral segment and terminating in said reinforcement second end, wherein the urethral segment is contained substantially entirely in the urethra, and the bladder segment is contained substantially entirely in the bladder, when the suppository is inserted into the female urethra; and

c. a meltable portion formed around the entire length of said reinforcement, said meltable portion comprising a taper region formed around said reinforcement urethral segment and an extension region formed around the reinforcement bladder segment, said taper region of the meltable portion having a diameter which tapers toward said reinforcement first end such that the taper occupies substantially the extent of the meltable portion from the second end of the reinforcement to the first end of the reinforcement, and said non-meltable base member being immobile with respect to the meltable portion;

said base member having a width in one direction perpendicular to the reinforcement, which width is greater than the maximum width of the meltable portion in a direction perpendicular to the reinforcement.

34. (Original) The urethral suppository of claim 33 wherein said base member is shaped for handling by a user of said suppository.

35. (Currently amended) A urethral suppository for insertion into a female urethra, said suppository comprising:

a. a non-meltable base member not for insertion into said urethra, said base member having a surface;

b. a non-meltable reinforcement having a length, a first end attached to the base and a second end distal from the base, said reinforcement projecting from the base and comprising a urethral segment extending from said first end and a bladder segment extending from said urethral segment and terminating in said reinforcement

second end, wherein the urethral segment is contained substantially entirely in the urethra, and the bladder segment is contained substantially entirely in the bladder, when the suppository is inserted into the female urethra; and

c. a meltable portion formed around the entire length of said reinforcement, said meltable portion comprising a taper region formed around said reinforcement urethral segment and an extension region formed around the reinforcement bladder segment, said taper region meltable portion having a diameter which tapers toward said reinforcement first end such that the taper occupies substantially the extent of the meltable portion from the second end of the reinforcement to the first end of the reinforcement, and said non-meltable base member being immobile with respect to the meltable portion, wherein said base member is an ellipsoid having a major axis substantially perpendicular to the longitudinal axis of the reinforcement.

36. (Original) The urethral suppository of claim 35, wherein said ellipsoid is curved to promote maximal penetration of the meltable portion in the urethra.

37. (Original) The urethral suppository of claim 33 wherein the surface of said base member is grooved to facilitate handling by a user.

38. (Previously presented) The urethral suppository of claim 33 wherein the surface of said base member is roughened to reduce slippage of the suppository during insertion.

39. (Previously presented) The urethral suppository of claim 33 wherein said base member fits within the labia minora of a patient.

40. (Original) The urethral suppository of claim 33 wherein said base member is formed from one or more materials selected from the group consisting of synthetic polymer, urethane, cellulose, glass, metal, rubber, and cloth.



41. (Original) The urethral suppository of claim 33 wherein said reinforcement projects substantially perpendicular from said base member.

42. (Previously presented) The urethral suppository of claim 33 wherein said reinforcement comprises a shape selected from the group consisting of ratchet, helix, cone and solid rod.

43. (Original) The urethral suppository of claim 42 wherein said shape is comprised of a lattice or mesh.

44. (Original) The urethral suppository of claim 33 wherein said reinforcement is formed from one or more materials selected from one or more of the groups consisting of urethane, cellulose, glass, metal, rubber, and cloth.

45. (Original) The urethral suppository of claim 33 wherein said reinforcement comprises one or more restraints formed along said portion of said length of said reinforcement.

46. (Original) The urethral suppository of claim 45 wherein said restraints are selected from one or more of the group consisting of protrusions and intrusions.

47. (Original) The urethral suppository of claim 46 wherein said protrusions are selected from one or more of the group of shapes consisting of spheres, hemispheres, triangles, rectangles, plates, and rods.

48. (Original) The urethral suppository of claim 46 wherein said intrusions are selected from one or more of the group of shapes consisting of spheres, hemispheres, triangles, rectangles, plates, and rods.

49. (Original) The urethral suppository of claim 33 wherein said meltable portion comprises one or more materials selected from the group consisting of theobroma oil and modified theobroma oil products, glycerinated gelatin, hydrogenated vegetable oils, cellulose, poly (vinyl alcohol), poly (vinylpyrrolidone), polyacrylamide, poly (ethylene glycol), poly (phospho urethanes), polyoxyl stearate and ethylenoxide polymers.

50. (Original) The urethral suppository of claim 33 wherein said meltable portion comprises one or more therapeutic agents selected from one or more of the group of agents consisting of antibiotics, antimicrobials, antifungals, analgesics, anesthetics, steroidal anti-inflammatories, non-steroidal anti-inflammatories, mucous production inhibitors, hormones, and antispasmodics.

51. (Original) The urethral suppository of claim 33 wherein the maximum diameter of the meltable portion formed around the urethral region is in the range of about 5 to about 12 millimeters.

52. (Original) The urethral suppository of claim 33 wherein the diameter of the meltable portion formed around the first end is in the range of about 4 to about 10 millimeters.

53. (Original) The urethral suppository of claim 33 wherein grooves are formed in said meltable portion.

54. (Previously presented) The urethral suppository of claim 53 wherein said grooves are parallel to a longitudinal axis of the meltable portion.

55. (Previously presented) The urethral suppository of claim 53 wherein said grooves are helical.

56. (Previously presented) The urethral suppository of claim 53 wherein said grooves form a passage for liquid melted from said meltable portion.

57. (Original) The urethral suppository of claim 33 wherein the length of said taper region is from about 2.5 cm to about 5.0 centimeters.

58. (Original) The urethral suppository of claim 33 wherein upon insertion, said meltable portion melts within about 2 minutes to about 60 minutes.

59. (Previously presented) The urethral suppository of claim 33 wherein the length of said reinforcement is in the range of about 40.0mm to about 80.0mm.

60. (Previously presented) The urethral suppository of claim 59 wherein said reinforcement has a diameter in the range of about 0.5mm to about 2.0mm.

61. (Currently amended) A method for delivering one or more therapeutic agents to the female urinary tract, said method comprising the steps of: a. inserting a urethral suppository into the urethra of a female patient; b. waiting a sufficient period for said suppository to deliver one or more therapeutic agents to said urinary tract; and c. removing the non-meltable reinforcement from the urethra;

wherein the urethral suppository comprises a non-meltable base member not for insertion into said urethra, said base member having a surface; a non-meltable reinforcement having a length, said length having a first end and a second end, said first end attached to said base member and projecting from said base member; and a meltable portion formed around said length of said reinforcement, said meltable portion having a diameter which tapers from said reinforcement second end toward said reinforcement first end such that the taper occupies substantially the extent of the meltable portion from the second end of the reinforcement to the first end of the reinforcement, said meltable portion for insertion into said urethra, said non-meltable base member being immobile with respect to the meltable portion and being wider than the meltable portion.

62. (Original) The method of claim 61 wherein the period ranges from about 1 minutes to about 10 hours.

63. (Original) The method of claim 61 wherein the period ranges from about 2 minutes to about 2 hours.

64. (Original) The method of claim 61 wherein said insertion step comprises grasping the suppository by the non-meltable base member, and positioning the suppository into the urethra wherein the base member sits completely within the labia minora.

65. (Withdrawn) A method for manufacturing a reinforced urethral suppository comprising the steps of:

- a. fabricating a single-unit comprising a non-meltable base member sized to prevent insertion of said base member into a female urethra, and a non-meltable reinforcement having a length, said length having a first end and a second end, said first end attached to and projecting from said base member;
- b. forming a meltable portion having a distal end and a proximal end, said meltable portion having a diameter which tapers from said distal end to said proximal end, and comprising one or more therapeutic agents and biocompatible material; and
- c. combining said non-meltable unit with said meltable portion whereby said meltable portion surrounds a portion of the length of said non-meltable reinforcement.

66. (Withdrawn) The method of claim 65 wherein said non-meltable base member and said non-meltable reinforcement are fabricated in a single step.

67. (Withdrawn) The method of claim 65 wherein said non-meltable base member and said non-meltable reinforcement are fabricated separately, and combined to form said single unit.

68. (Withdrawn) The method of claim 65 wherein said step of combining involves molding said meltable portion around said non-meltable reinforcement.

69. (Withdrawn) The method of claim 65 wherein said step of combining involves inserting said reinforcement into said meltable portion.

70. (Withdrawn) The method of claim 65 wherein said base member and said reinforcement are independently formed from one or more material selected from the group consisting of synthetic polymer, urethane, cellulose, glass, metal, rubber, and cloth.

71. (Withdrawn) The method of claim 65 wherein said meltable portion comprises one or more materials selected from the group consisting of theobroma oil and modified theobroma oil products, glycerinated gelatin, hydrogenated vegetable oils, cellulose, poly (vinyl alcohol), poly (vinylpyrrolidone), polyacrylamide, poly (ethylene glycol), poly (phospho urethanes), polyoxyl stearate and ethylenoxide polymers.

72. (Withdrawn) The method of claim 71 wherein said meltable portion further comprises one or more therapeutic agents selected from one or more of the group of agents consisting of antibiotics, antimicrobials, antifungals, analgesics, anaesthetics, steroidal anti-inflammatories, non-steroidal anti-inflammatories, mucous production inhibitors, hormones, and antispasmodics.

73. (Previously presented) The urethral suppository of claim 1 wherein said reinforcement has a length in the range of about 25.0mm to about 80.0mm.

74. (Previously presented) The urethral suppository of claim 1 wherein the length of said reinforcement is in the range of about 25.0mm to about 40.0mm.

75. (Previously presented) The urethral suppository of claim 33 wherein the length of said reinforcement is in the range of about 25.0mm to about 40.0mm.

76. (Currently amended) A method for delivering one or more therapeutic agents to the female urinary tract, said method comprising the steps of: a. inserting a urethral suppository into the urethra of a female patient; b. waiting a sufficient period for said suppository to deliver one or more therapeutic agents to said urinary tract; and c. removing the non-meltable reinforcement from the urethra;

wherein the urethral suppository comprises a non-meltable base member not for insertion into said urethra, said base member having a surface; a non-meltable reinforcement having a length, a first end attached to the base and a second end distal from the base, said reinforcement projecting from the base and comprising a urethral segment extending from said first end and a bladder segment extending from said urethral segment and terminating in said reinforcement second end, wherein the urethral segment is contained substantially entirely in the urethra, and the bladder segment is contained substantially entirely in the bladder when the suppository is inserted into the female urethra; and a meltable portion formed around the entire length of said reinforcement, said meltable portion comprising a taper region formed around said reinforcement urethral segment and an extension region formed around the reinforcement bladder segment, said taper region meltable portion having a diameter which tapers toward said reinforcement first end such that the taper occupies substantially the extent of the meltable portion from the second end of the reinforcement to the first end of the reinforcement, said non-meltable base member being immobile with respect to the meltable portion and being wider than the meltable portion.

77. (Previously presented) The method of claim 76 wherein the period ranges from about 1 minutes to about 10 hours.

78. (Previously presented) The method of claim 77 wherein the period ranges from about 2 minutes to about 2 hours.

79. (Previously presented) The method of claim 76 wherein said insertion step comprises grasping the suppository by the non-melttable base member, and positioning the suppository into the urethra wherein the base member sits completely within the labia minora.